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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,556	11/06/2003	Chandralata Raghukumar	Q78361	8327
23373 7590 02/15/2007 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER MARX, IRENE	
			ART UNIT 1651	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/15/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/701,556

Applicant(s)

RAGHUKUMAR ET AL.

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1651

DETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group III, claims 16-21 on 11/27/06 is acknowledged.

Claims 16-21 are being considered on the merits. Claims 1-15 and 22 are withdrawn from consideration as directed to a non-elected invention.

Contrary to applicant's indication, a separate list in compliance with 37 CFR 1.98(a)(1) on a PTO/SB/08A and 08B form is not of record. This form must be filed within the set period for reply to this Office action, alternatively, it is recommended that a form 1449 be filed to assure that the documents are listed on any patent that matures from this application. The references as filed have been considered, but will not be listed on any patent resulting from this application.

A substitute specification is required pursuant to 37 CFR 1.125(a) because the as-filed specification is defective as being barely legible.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Art Unit: 1651

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific fungal strain. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 6 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

Art Unit: 1651

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is confusing in the recitation of "low temperature", since the degree of "low" is unclear in this context. The term is ambiguous and open to interpretation. Also, it is unclear whether the property pertains to the enzyme or to the producing microorganism.

Claim 16 lacks internal antecedent basis for "the experimental medium". In addition there is no clear indication as to the composition of this medium.

In claim 16 the sole designation of a microorganism by its internal designation be it a name or number is arbitrary and creates ambiguity in the claims. For example, the microorganism disclosed in this application could be designated by some other arbitrary means,

Art Unit: 1651

or the assignment of the microorganism name or number could be arbitrarily changed to designate another microorganism. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to the genus/species and deposit accession number of the claimed microorganism would obviate this rejection.

Claim 16 is vague and indefinite in the recitation of "shallow static culture", since the term "shallow" is ambiguous and open to interpretation. It is unclear, for example, whether the culturing requires a liquid or a solid substrate?

The genus of the fungal strain should also be inserted into claim 16 to clarify the invention.

Claim 17 lacks antecedent basis for "the fungus *Aspergillus* sp. bearing international deposition number".

Claims 18-19 lack antecedent basis for "the fungus" or "said fungus". In claim 16 it is designated as a fungal strain.

Claims 18-19 are vague and indefinite in the recitation of "can be grown". This is not a positive recitation of a claim limitation.

Claim 20 lacks clear antecedent basis for "the culture media". It is unclear which culture medium is intended. (a) or (c) (d) or all.

Claim 21 is vague and indefinite in that the designation of "Czapek Dox broth" does not appear to be an art recognized culture broth with a specific composition. See, e.g., *Microbiological Media*, pages 279-280. Also, the claim appears incomplete in that there is no clear indication as to which ingredients must be added and which are optional. In this regard, it is unclear what constitutes "spray-dried dairy whitener". The antecedent basis for "independently at 1%" is uncertain and it is also unclear as to which nutrients are to be encompassed. Also there is no indication if this 1% is by weight or by volume.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1651

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nehra *et al.* taken with Sindhu *et al.*, Malathi *et al.* and Atlas *et al.*

The claims are directed to a process of producing a low temperature alkaline protease with a specific *Aspergillus* strain using certain conditions.

Nehra *et al.* disclose the production of an alkaline protease with an *Aspergillus* strain, wherein the fungal mat was used to obtain a starter culture and submerged fermentation, which is presumed to be "shallow" and which appear to be static. See, e.g., page 44, Results and Discussion. In addition, Nehra *et al.* disclose various nitrogen sources, including soybean meal and casein, for example.

The process differs from the claimed invention in the use of certain culture medium additives. However, Malathi *et al.* adequately demonstrate that the use of malt extract, corn steep liquor, and soybean meal are all old and well known additives used for the cultivation of *Aspergillus* for the production of alkaline proteases. See, e.g., page 714, Table I. The alkaline protease produced appears to constitute a "low temperature" alkaline protease in that loss of activity occurs at 32° C as compared with 28° C.

The process further differs from the claimed invention in that the properties of the strain cultured in Nehra *et al.* and Malathi *et al.* are not clearly delineated. However, inasmuch as the strains belong to the same genus *Aspergillus*, it is apparent that they are substantially similar.

In addition, Sindhu *et al.* disclose the production of alkaline protease by various fungi, several of which are *Aspergillus* strain. See, e.g., page 27, Table II.

The use of "Czapek Dox broth" in the cultivation of *Aspergillus* is old and well known in the art. See, e.g., Atlas *et al.*, pages 279-280. Moreover, the use of glucose in the medium is

Art Unit: 1651

disclosed by Nehra *et al.*, page 44, Table 1 and *Aspergillus* are recognized in the art as cellulase producers.

The process conditions discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Nehra *et al.* and Malathi *et al.* by culturing further *Aspergillus* strains as suggested by the teachings of Sindhu *et al.* and adjusting process conditions to optimize the protease production for the expected benefit of maximizing production of useful low temperature alkaline proteases for various industrial and pharmaceutical applications, including as a depilation agent.

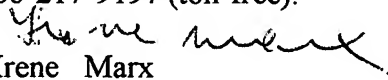
Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651